

**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

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LLOYD BUNTING AND THELMA BUNTING,

Plaintiffs,

v.

BRISTOL-MYERS SQUIBB COMPANY,  
SANOFI-AVENTIS U.S. L.L.C.,  
SANOFI-AVENTIS U.S., INC.,  
SANOFI-SYNTHELABO, INC.,

Defendants.

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: Civil Action No. 3:06-cv-6052 (FLW)  
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**OPINION**

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This matter comes before the Court on a motion to dismiss pursuant to Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure brought by defendants, Bristol Myers-Squibb Company, Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc., (collectively, “Defendants”). Plaintiffs Lloyd and Thelma Bunting’s<sup>1</sup> First Amended Complaint asserts claims against Defendants for: (1) products liability - design (Count I); (2) products liability - manufacture (Count II); (3) products liability - failure to warn (Count III); (4) negligence (Count IV); (5) negligent misrepresentation (Count V); (6) violations of Colorado’s Consumer Protection Act (Count VI); and (7) loss of consortium (Count VII). Plaintiff alleges that he was injured as a result of Defendants’ unlawful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and sale of the prescription drug Plavix®.

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<sup>1</sup> Thelma Bunting asserts a loss of consortium claim. For simplicity, since the loss of consortium claim is derivative of Lloyd Bunting’s claims, two of which are the subject of the instant motion, references to “Plaintiff” in this opinion will be in the singular.

Defendants' motion to dismiss is limited to Counts V and VI of Plaintiff's Complaint. For the reasons that follow, Counts V and VI are dismissed without prejudice.

## **I. Procedural History**

On December 18, 2006, Plaintiff, a Colorado resident, filed a Complaint against Defendants asserting claims under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, *et seq.*, the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq.*, the New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.9, *et seq.*, New Jersey's Uniform Commercial Code, N.J.S.A. 12A:2-313, and the common law of the State of New Jersey, invoking this Court's diversity jurisdiction. (Dec. 18, 2006 Complaint ¶¶ 6-8.) Plaintiff is one of twenty-three individual claimants<sup>2</sup> that lodged separate complaints<sup>3</sup> against Defendants in this district between October 2006 and March 2007, invoking this Court's diversity jurisdiction and asserting similar claims under New Jersey law based upon injuries allegedly suffered as a result of Defendants' alleged negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and/or the sale of Plavix. *Id.* A brief recitation of the procedural history in the related matters is necessary to a full understanding of the prolonged procedural history in this matter.

In January 2007, Defendants filed motions to dismiss pursuant to Fed.R.Civ.P. 12(b)(6) in the matters of Hall v. Bristol-Myers Squibb, No. 06-CV-5203 (hereinafter,

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<sup>2</sup> Initially, claims were filed on behalf of twenty-four individual claimants, however, a Michigan plaintiff in the matter of Felmlee v. Bristol-Myers Squibb Co., No. 06-6240, voluntarily dismissed her claim in February, 2008.

<sup>3</sup> A number of the twenty-three claimants were joined in their actions by spouses, asserting claims for loss of consortium.

“Hall”), and Skilstaff v. Bristol-Myers Squibb, No. 06-CV-4965 (hereinafter, “Skilstaff”),<sup>4</sup> and indicated their intention to file similar motions in the other Plavix cases pending before this Court. In March 2007, this Court, without objection from the parties, administratively terminated Defendants’ motions in Hall and Skilstaff having determined that two cases then pending before the New Jersey Supreme Court addressed the central issues to be decided by this Court on Defendants’ motions to dismiss. The parties further agreed that all Plavix cases filed in this district be held in abeyance. Following the issuance of the New Jersey Supreme Court’s decisions in Rowe v. Hoffman-LaRoche, 189 N.J. 615 (2007), and International Union of Operating Engineers, Local #68 v. Merck, 192 N.J. 372 (2007), the plaintiff in Skilstaff voluntarily dismissed the action and this Court granted Defendants’ request to file a single omnibus motion to dismiss applicable to all personal injury Plavix lawsuits then pending in this district.

One of the main issues to be determined by this Court in the omnibus motion was the federal preemption of the plaintiffs’ individual state law claims. In February 2008, however, in light of the fact that the Third Circuit had pending two separate cases, Colacicco v. Apotex, Inc., and McNellis ex. rel. DeAngelis v. Pfizer, Inc., on its docket regarding substantially similar preemption issues, as did the United States Supreme Court, Levine v. Wyeth, this Court administratively terminated the personal injury Plavix cases pending in this district and permitted plaintiffs to re-file amended complaints in the event there were viable claims after the decisions from the Higher Courts. Following the

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<sup>4</sup> The plaintiff in the matter of Skilstaff v. Bristol-Myers Squibb, is not among the twenty-three individual claimants seeking damages for personal injuries, rather Skilstaff was an Alabama third-party payor seeking certification of a class of third-party payors for violations of the New Jersey Consumer Fraud Act.

issuance of the Supreme Court's decision in Levine v. Wyeth, \_\_ U.S. \_\_, 129 S.Ct. 1187, 173 L.Ed. 2d 51 (2009), this Court reinstated the closed cases and, on May 1, 2009, each of the plaintiffs filed an amended complaint. In the amended complaints, each individual plaintiff brought claims under the laws of the states in which they reside, rather than New Jersey, as originally plead. Thereafter, Defendants moved to dismiss certain counts of the amended complaint filed by each individual plaintiff. It is the Defendants' motion to dismiss Counts V and VI with regard to this Plaintiff that this Court now considers.

## **II. Factual Background**

The following version of events assumes Plaintiff's allegations in the First Amended Complaint ("FAC") to be true because Defendants move pursuant to Fed.Civ.R.P. 12(b)(6). The Court will recount only those facts relevant to this Motion.

Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc. (collectively, the "Sanofi Defendants") partnered with Bristol-Myers Squibb Company ("BMS") to manufacture and market Plavix in the United States. FAC ¶¶ 2-5. In April 1997, the Sanofi Defendants and BMS applied for a rare, priority regulatory review by the Food and Drug Administration ("FDA") clearing the way for Defendants to bring Plavix to market in November 1997. Id. at ¶ 12. According to Plaintiff, Defendants heavily marketed Plavix directly to consumers through television, magazine, and Internet advertising, falsely touting Plavix "as a 'super-aspirin' that would give a person even greater cardiovascular benefits than a much less expensive, daily aspirin, while being safer and easier on a person's stomach than aspirin." Id. at ¶ 14. Plaintiff alleges that Defendants either knew or should have known, based upon their own studies, that not only was Plavix not more efficacious than aspirin in terms of preventing heart attacks and

strokes, the risk of suffering a heart attack, stroke, internal bleeding, blood disorder or death far outweighed any benefit from the drug. Id. at ¶ 15.

As evidence that Defendants were indeed aware of their false and misleading promotion of Plavix, Plaintiff points to a November 1998 letter from the FDA wherein the FDA instructed Defendants to cease promoting Plavix for off-label use in patients undergoing coronary artery stent placement.<sup>5</sup> Id. at ¶ 19; Certification of Michele A. DiMartino, Esq. (“DiMartino Cert.”) at ¶ 4, Ex. C. Plaintiff also points to the same FDA reprimand wherein Defendants were instructed to cease promoting Plavix at an off-label dose, which was nearly four (4) times that of the recommended dosage. FAC at ¶ 19; DiMartino Cert. ¶ 4, Ex. C. In addition to criticizing Defendants for promoting Plavix for unapproved use, the FDA also criticized Defendants for overstating the safety profile of Plavix with respect to its use with other drugs. Id. at ¶ 20. In particular, Plaintiff points to the fact that Defendants touted the safety of Plavix when combined with aspirin (known as “dual therapy”) when, in fact, its safety had not been established. Id. According to Plaintiff, Defendants’ claim regarding the safety of dual therapy has now been proven to be untrue in a recent study published in the New England Journal of Medicine in April 2006 entitled Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance (the “CHARISMA Study”<sup>6</sup>). FAC at ¶ 20; DiMartino Cert. at ¶ 3, Ex. B.

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<sup>5</sup> As discussed more fully infra, the Court will consider the extrinsic documents referenced in the FAC as they were explicitly relied upon by Plaintiff in the FAC.

<sup>6</sup> The CHARISMA Study derives its name from the Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance trial, which was the subject of the article.

As further evidence of Defendants' allegedly false and misleading promotional practices, Plaintiff points to a December 1998 letter from the FDA, wherein the FDA demanded that Defendants cease the distribution of advertising materials that claimed that Plavix has been proven more effective than aspirin. FAC at ¶ 21; DiMartino Cert. at ¶ 2, Ex. A. The FDA criticized Defendants' materials as an overstatement of efficacy, which was unsubstantiated and lacking in fair balance. Id. Again in 2001, the FDA ordered Defendants to immediately cease distribution of promotional material that made false or misleading claims about Plavix. FAC at ¶ 22; DiMartino Cert. at ¶ 5, Ex. D. Specifically, the FDA noted that the clinical evidence of the efficacy of Plavix is derived from Defendants' study entitled Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events Trial (the "CAPRIE Study"). Id. Defendants' promotional material depicted a 19.2% relative risk reduction for Plavix versus aspirin, yet the actual findings of the CAPRIE Study were that Plavix was not proven significantly more effective than aspirin. Id. Additionally, the FDA again instructed Defendants to cease claiming that the use of Plavix combined with aspirin was safe and effective. Id.

According to Plaintiff, in addition to misinforming physicians and consumers through false and misleading promotional materials and advertising, Defendants' drug representatives also misinformed physicians regarding the proper types of patients who should be prescribed Plavix, the duration of its proper usage and the applications for which Plavix is safe and FDA approved. FAC at ¶ 23. Specifically, Plaintiff points to the fact that the drug representatives have encouraged physicians to prescribe Plavix to a broad population who would receive the same therapeutic benefit from aspirin alone, without the purported risk of death, and to use Plavix for unapproved applications. Id. at ¶ 24.

Plaintiff alleges that after a nearly eight-year run of misleading physicians and the public regarding the safety and efficacy of Plavix, scientific studies now reveal that Plavix is in fact dangerous. Id. at ¶ 26. Citing a study published in The New England Journal of Medicine in January 2005 entitled Clopidogrel versus Aspirin and Esomeprazole to Prevent Recurrent Ulcer Bleeding (the “Chan Study”), Plaintiff notes the dangers of Plavix.

Specifically, Plaintiff contends that the Chan Study demonstrates the fallacy of Defendants’ assertions that Plavix is safer and more effective for patients suffering from gastrointestinal intolerance to aspirin. Id. at ¶ 27. Plaintiff points out that the Chan Study recommended that prescribing guidelines for Plavix be changed so that patients would not erroneously believe that Plavix is safer on the stomach than aspirin, in light of the Study’s findings that recurring stomach bleeding was 8.6% in the Plavix group versus only .7% in the aspirin group. Id. Plaintiff additionally points to the Chan Study’s finding that an aspirin a day plus esomeprazole (the generic name for an inexpensive over-the-counter proton pump inhibitor such as Prilosec) is far more cost effective than paying for the four-dollar per day Plavix pill, which greatly increases the risk of stomach bleeding. Id. at ¶ 28. Finally, citing the CHARISMA Study, Plaintiff contends that Plavix plus aspirin (“dual therapy”) is only minimally more effective than aspirin plus placebo at preventing atherothrombotic events, and more significantly, does more harm than good in those patients without peripheral arterial disease or acute coronary syndrome in that it poses a 20% increased risk to the patient of suffering bleeding injuries, heart attacks, stroke and death. Id. at ¶ 29.

Plaintiff Lloyd Bunting contends that he “had been prescribed dual therapy (Plavix plus a daily aspirin) around April, 2003 by his physician following a mini stroke that left

his left leg slightly paralyzed and at the time he only needed the assistance of a cane to walk. Lloyd Bunting continued on dual therapy of Plavix plus a daily aspirin until May, 2004 when he complained on [sic] flu-like symptoms and shortly after, was found by his wife in a pool of blood, having suffered a severe internal hemorrhage. Lloyd Bunting was rushed to the ER, where he was intubated and given blood transfusions. He had to be transported to Pueblo, Colorado, for intensive care. After several attempts to find the source of bleeding it was determined to be in his abdomen and repaired. Mr. Bunting required many additional units of blood to be transfused. Lloyd Bunting nearly lost his life and stayed in the hospital for a total of three weeks. He has still not made a complete recovery; never having regained his strength and, also, having lost his mobility. Where he could walk with just the assistance of a cane before the hemorrhage, he now must use a walker, or be pushed in a wheelchair by his wife, Thelma Bunting.” *Id.* at ¶ 31. With regard to his own experiences, or those of his prescribing physician, in connection with Defendants’ purported false and misleading promotional materials and practices, Plaintiff’s limited discussion of those facts will be discussed more fully infra.

### **III. Standard of Review**

When reviewing a motion to dismiss on the pleadings, courts "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008) (citation and quotations omitted). In Bell Atlantic Corporation v. Twombly, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), the Supreme Court clarified the 12(b)(6) standard. Specifically, the Court "retired" the language contained in Conley v. Gibson, 355 U.S. 41,



45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Id. at 561 (quoting Conley, 355 U.S. at 45-46). Instead, the factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." Id. at 555. As the Third Circuit has stated, "[t]he Supreme Court's Twombly formulation of the pleading standard can be summed up thus: 'stating ... a claim requires a complaint with enough factual matter (taken as true) to suggest' the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of 'the necessary element'." Phillips, 515 F.3d at 234 (quoting Twombly, 550 U.S. at 556).

In affirming that Twombly standards apply to all motions to dismiss, the Supreme Court recently explained the principles. "First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949, 173 L.Ed. 2d 868 (2009); Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009).<sup>7</sup> "Second, only a complaint that states a plausible claim for relief survives a motion to dismiss." Id. at 1950. Therefore, "a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." Id. Ultimately, "a complaint must do more than allege the plaintiff's entitlement to relief. A

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<sup>7</sup> The Court notes that because the briefing in this matter was filed only shortly after the United States Supreme Court's decision in Ashcroft v. Iqbal, 129 S. Ct. 1937 (2009), counsel for Defendants moved for leave to file supplemental briefing addressing the standard of review applicable to the instant motion. This Court found additional briefing unnecessary and, accordingly, denied Defendants' request.

complaint has to ‘show’ such an entitlement with its facts.” Fowler, 578 F.3d at 211.

Before reaching the merits of Plaintiff’s claims, there is a threshold procedural question as to the documents and exhibits this Court may consider on this motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(6). As previously referenced in this Court’s discussion of the Factual Background, Plaintiff supplies this Court with several exhibits, including: (1) a December 1998 FDA letter addressed to Sanofi Pharmaceuticals, Inc.; (2) a copy of the CHARISMA Study; (3) a November 1998 FDA letter addressed to Sanofi Pharmaceuticals, Inc.; (4) a May 2001 FDA letter addressed to Sanofi-Synthelabo Inc.; and (5) the Chan Study. Additionally, the Defendants provide the Court with the November 17, 1997 approval letter for Plavix. Certification of Michael A. Tanenbaum, Esq., Ex. A. While generally a court may not consider matters outside the pleadings when ruling on a motion to dismiss, documents that are “integral to or explicitly relied upon in the complaint” may indeed be considered without converting a motion to dismiss into a motion for summary judgment. In re Rockefeller Ctr. Props., Inc. Sec. Litig., 184 F.3d 280, 287 (3d Cir.1999) (emphasis and citations omitted). Accordingly, the referenced exhibits are properly before the Court on the instant motion to dismiss.

#### **IV. Plaintiff’s Claim Under Colorado’s Consumer Protection Act**

In Count VI of Plaintiff’s FAC, Plaintiff asserts violations of Colorado’s Consumer Protection Act, Colo. Rev. Stat. § 6-1-101 *et seq.* (“CCPA”). “The CCPA was enacted to regulate commercial activities and practices which, ‘because of their nature, may prove injurious, offensive, or dangerous to the public. . . . The CCPA deters and punishes businesses which commit deceptive practices in their dealings with the public by providing prompt, economical, and readily available remedies against consumer fraud.” Rhino

Linings USA, Inc. v. Rocky Mountain Rhino Lining, Inc., 62 P.3d 142, 146 (Colo. 2003) (*internal citations omitted*). “To prove a private claim for relief under the CCPA, a plaintiff must show: (1) that the defendant engaged in an unfair or deceptive trade practice; (2) that the challenged practice occurred in the course of defendant’s business, vocation, or occupation; (3) that it significantly impacts the public as actual or potential consumers of the defendant’s goods, services or property; (4) that the plaintiff suffered injury in fact to a legally protected interest; and (5) that the challenged practice caused the plaintiff’s injury.” Crowe v. Tull, 126 P.3d 196, 201 (Colo. 2006).

Defendants seek dismissal of Plaintiff’s CCPA claim, arguing that Plaintiff has failed to satisfy the elements required to establish a claim under the CCPA. Specifically, Defendants point to the fifth element of Plaintiff’s CCPA claim, which requires him to demonstrate causation. Defendants assert that Plaintiff merely alleges that “[a]s a direct and proximate result of the Deceptive Trade Practices committed by Defendants as alleged above, Plaintiff suffered and will continue to suffer injuries, damages and losses.” Def. Br. at 4 (citing FAC at ¶ 73). Defendants also assert that Plaintiff’s CCPA claim fails to satisfy the particularity requirements of Fed.R.Civ.P. 9(b) in that it fails to identify “(1) the specific advertisements that reached Mr. Bunting; (2) how he was misled by these advertisements; (3) how these advertisements affected the prescription of Plavix for him; and (4) how these advertisements caused any of his injuries.” Def. Br. at 6.

In Frederico v. Home Depot, 507 F.3d 188 (3d Cir. 2007), the Third Circuit elucidated what must be alleged to satisfy the heightened pleading standard of Rule 9(b):

Pursuant to Rule 9(b), a plaintiff alleging fraud must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the “precise misconduct with which [it is] charged.” To satisfy this standard, the plaintiff must plead or allege the date, time and place of the alleged fraud or

otherwise inject precision or some measure of substantiation into a fraud allegation. Id. at 200 (internal citations omitted). The Court finds the FAC woefully deficient. As Defendants indicate, Paragraph 31 of the FAC is the only paragraph in the entire FAC that provides specific details regarding Plaintiff and not one of those details concerns the CCPA claim.<sup>8</sup> The remaining factual allegations are boilerplate allegations that, as Defendants point out, appear in all twenty-three of the amended complaints filed by the personal injury Plavix plaintiffs in this district. The allegations within Count VI of the FAC do not remedy the deficiency. The allegations amount to nothing more than a mechanical recitation of the elements of a cause of action under the CCPA. Indeed, there is absolutely no plaintiff-specific information identified in Count VI.

Plaintiff's response to Defendants' contention that he has failed to satisfy the pleading requirements of 9(b) are set forth in one paragraph in his Opposition Brief wherein he cites only Paragraph 31 as supportive of the fact that he has suffered an actual injury and that the injury was caused by Defendants' actions. Pl. Br. at 5. Even assuming that Plaintiff has plead with particularity with respect to the other four elements of the

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<sup>8</sup> As previously noted, Paragraph 31 provides that Plaintiff "had been prescribed dual therapy (Plavix plus a daily aspirin) around April, 2003 by his physician following a mini stroke that left his left leg slightly paralyzed and at the time he only needed the assistance of a cane to walk. Lloyd Bunting continued on dual therapy of Plavix plus a daily aspirin until May, 2004 when he complained on [sic] flu-like symptoms and shortly after, was found by his wife in a pool of blood, having suffered a severe internal hemorrhage. Lloyd Bunting was rushed to the ER, where he was intubated and given blood transfusions. He had to be transported to Pueblo, Colorado, for intensive care. After several attempts to find the source of bleeding it was determined to be in his abdomen and repaired. Mr. Bunting required many additional units of blood to be transfused. Lloyd Bunting nearly lost his life and stayed in the hospital for a total of three weeks. He has still not made a complete recovery; never having regained his strength and, also, having lost his mobility. Where he could walk with just the assistance of a cane before the hemorrhage, he now must use a walker, or be pushed in a wheelchair by his wife, Thelma Bunting." Id. at ¶ 31.

CCPA claim, he has failed to sufficiently plead the fifth element – that the alleged deceptive practices were the proximate cause of Plaintiff's injury. The FAC fails to allege with specificity the connection between Defendants' conduct and Plaintiff's injury.

Significantly, the facts necessary to satisfy Rule 9(b) are not facts which are in Defendants' control. Rather, what Plaintiff has failed to allege are those facts that demonstrate that either Plaintiff or his prescribing physician personally received or viewed any of the purported misrepresentations and/or omissions.<sup>9</sup> Plaintiff has failed to plead any nexus between the alleged deceptive acts and the injury. Plaintiff alleges simply that “[a]s a direct and proximate result of the Deceptive Trade Practices omitted by Defendants as alleged above, Plaintiff suffered and will continue to suffer as alleged herein.” FAC at ¶ 73. Plaintiff does not even identify the name of the prescribing physician. While it is true that when reviewing a motion to dismiss, the Court must construe the complaint in the light most favorable to the plaintiff, Phillips, 515 F.3d at 233, in the absence of specific facts in the FAC that Plaintiff or his prescribing physician ever even viewed the promotional materials that the FDA demanded Defendants discontinue disseminating three to six years prior to Plaintiff's prescription, the Court simply cannot find the

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<sup>9</sup> Indeed, in that connection, Plaintiff is uniquely equipped to determine from his prescribing physician, whether the physician received such promotional literature or information from Defendants' sales representatives. Even where factual information may be within the domain or control of Defendants, Plaintiff must still “accompany [his] legal theory with factual allegations that make [his] theoretically viable claim plausible.” In re Burlington Coat Factory, 114 F.3d 1410, 1418 (3d Cir. 1997). Moreover, to “avoid dismissal,” a complaint must also delineate at least the nature and the scope of a plaintiff's efforts to obtain, before filing the complaint, the information needed to plead with particularity. Shapiro v. UJB Financial Corp., 964 F.2d 272, 285 (3d Cir. 1992). Plaintiff has failed to comply with these requirements. Plaintiff's FAC makes no allegations that the information required for Plaintiff to meet his Rule 9(b) obligation is solely within Defendants' control.

particularity requirements have been met with respect to causation. Accordingly, Plaintiff's CCPA claim cannot withstand the instant motion to dismiss and will be dismissed without prejudice.

## **V. Plaintiff's Negligent Misrepresentation Claim**

The formulation of the tort of negligent misrepresentation set forth in § 311 of the Restatement (Second) of Torts was first recognized by the Colorado Supreme Court in Bloskas v. Murray, 646 P.2d 907, 914 (Colo. 1982).

“Section 311 of the Restatement (Second) of Torts sets forth the elements of the claim:

### **Negligent Misrepresentation Involving Risk of Physical Harm**

(1) One who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results (a) to the other, or (b) to such third persons as the actor should expect to be put in peril by the action taken.

(2) Such negligence may consist of failure to exercise reasonable care (a) in ascertaining the accuracy of the information, or (b) in the manner in which it is communicated.

Id. (*quoting* Restatement (Second) of Torts § 311 (1965)). Accordingly, “[t]he tort of negligent misrepresentation is committed if a person ‘negligently gives false information’ to another and that other, acting in reasonable reliance upon such information, takes action that results in that other person’s physical harm.” Baily v. Huggins Diagnostic & Rehabilitation Center, Inc., 952 P.2d 768, 772 (Colo.App. 1998) (*quoting* Restatement (Second) of Torts § 311 (1993)). While the vast majority of courts addressing issues related to the tort of negligent misrepresentation under Colorado law have done so in cases involving pecuniary loss applying § 552 of the Restatement (Second) of Torts (1976),

Plaintiff does not dispute Defendants' assertion that to state a claim for negligent misrepresentation Plaintiff "must show that a defendant negligently gave false information to another and that information was justifiably relied upon and harm resulted." Def. Br. at 7.

Defendants contend that like the CCPA claim, Plaintiff's negligent misrepresentation claim is subject to the particularity requirements of Rule 9(b). Defendants argue that because Plaintiff's negligent misrepresentation claim sounds in fraud, the heightened standards of Rule 9(b) apply. While Defendants correctly cite Van Leeuwan v. Nuzzi, 810 F.Supp. 1120, 1123 (D.Colo. 1993) in support of the proposition that Rule 9(b) has been applied to a negligent misrepresentation brought under Colorado law, other courts considering the issue in the Tenth Circuit have found the particularity requirements of Rule 9(b) inapplicable to a negligent misrepresentation claim brought under Colorado law. See Conrad v. Education Resources Institute, \_\_ F.Supp. \_\_, No. 08-1393 (WYD), 2009 WL 2514161, \*10 (D.Colo. Aug. 13, 2009); City of Raton v. Arkansas River Power Authority, 600 F.Supp.2d 1130, 1142-43 (D.N.M. 2008). Nevertheless, this Court need not resolve the issue here because even under the more lenient standards of Rule 8(a), Plaintiff's negligent misrepresentation claim cannot withstand the instant motion to dismiss.<sup>10</sup>

Last year, addressing the clarifications as to a litigant's pleading requirement stated by the United States Supreme Court in Twombly, 550 U.S. 544, the Court of

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<sup>10</sup> The Court cautions that to the extent Plaintiff intends to seek this Court's leave to file a second amended complaint, it must be clearly averred that the claim is premised upon a theory of negligence, and does not sound in fraud, to avoid application of Rule 9(b).

Appeals for the Third Circuit provided the district courts with guidance as to what pleadings are sufficient to pass muster under Rule 8. See Phillips v. County of Allegheny, 515 F.3d at 230-34. Specifically, the Third Circuit, quoting Twombly, observed as follows:

“[W]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff’s [Rule 8] obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” . . . “[T]he threshold requirement of Rule 8(a)(2) [is] that the ‘plain statement’ possess enough heft to ‘sho[w] that the pleader is entitled to relief.’” . . . “Factual allegations must be enough to raise a right to relief above the speculative level.”

Phillips 515 F.3d at 231-32 (quoting Twombly 550 U.S. at 555). As previously noted, this pleading standard was further refined by the United States Supreme Court in Ashcroft v. Iqbal, 129 S. Ct. 1949 wherein the Supreme Court held that in all civil actions:

[T]he pleading standard Rule 8 announces . . . demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation. . . . The plausibility standard is not akin to a “probability requirement,” but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are “merely consistent with” a defendant’s liability, it “stops short of the line between possibility and plausibility of ‘entitlement to relief.’”

. . . .

Two working principles underlie [the] decision in Twombly. First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice. . . . Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions. Second, only a complaint that states a plausible claim for relief survives a motion to dismiss. Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well-pleaded facts do



not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not “show[n]” - “that the pleader is entitled to relief.” Fed. Rule Civ. Proc. 8(a)(2).

. . . .

Rule 8 does not empower [a claimant] to plead the bare elements of his cause of action, affix the label “general allegation,” and expect his complaint to survive a motion to dismiss.

Iqbal, 129 S.Ct. at 1949-54 (quoting Twombly 550 U.S. at 555-57). Since Iqbal, the Third Circuit has required the district courts to conduct, with regard to Rule 8 allegations, a two-part analysis when presented with a motion to dismiss:

First, the factual and legal elements of a claim should be separated. The District Court must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions. [See Iqbal, 129 S.Ct. at 1949-50]. Second, a District Court must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a “plausible claim for relief” [in light of the definition of “plausibility” provided in Iqbal.] In other words, a complaint must do *more than allege the plaintiff's entitlement to relief*. A complaint has to “show” such an entitlement with its facts. See Phillips, 515 F.3d at 234-35. As the Supreme Court instructed in Iqbal, “[w]here the well-pleaded facts do not permit the court to infer more than the *mere possibility of misconduct, the complaint has alleged-but it has not ‘show [n]’-‘that the pleader is entitled to relief.’*” Iqbal, 129 S.Ct. at 1949-50. This “plausibility” determination will be “a context-specific task that *requires the reviewing court to draw on its judicial experience and common sense.*” Id.

Fowler, 578 F.3d at 210-11 (emphasis supplied).

This Court finds that Plaintiff has failed to plead anything other than bald conclusory allegations in support of his negligent misrepresentation claim. As previously noted in connection with this Court’s discussion of Plaintiff’s CCPA claim, the only factual allegations in the FAC that provide details with regard to this Plaintiff are those

in Paragraph 31. However, in Paragraph 31 Plaintiff simply asserts the harm that he suffered. Plaintiff has failed to plead any facts to support his conclusory statements in Paragraphs 62 and 63 of the FAC that he justifiably relied on the information supplied by Defendants or that he suffered injuries as a result of his reliance on those alleged misrepresentations. It is not enough for Plaintiff to set forth a formulaic recitation of the elements of the tort and the purported omissions and representations referenced in the FDA correspondences, which directed Defendants to cease distribution of its misleading promotional materials three to six years prior to Plaintiff's prescription for Plavix. Accordingly, Plaintiff's negligent misrepresentation claim cannot withstand the instant motion to dismiss.

#### **VI. Conclusion**

For the foregoing reasons, Counts V and VI of Plaintiff's FAC are dismissed without prejudice. Plaintiff shall have leave to file a motion to amend the complaint if he seeks to assert the claims, but he must cure the deficiencies as outlined by the Court herein.

Dated: December 30, 2009

/s/ Freda L. Wolfson  
**United States District Judge**